

## REMARKS

With entry of this Amendment, claims 1-4, 6, 7, 11-14, 25, 26, 28, 29, 33, 34, 36, 37, 41, 42, 44, and 45 are pending in this application. Applicants have cancelled claims 5, 8-10, 15-24, 27, 30-32, 35, 38-40, 43, and 46-48 without prejudice to or disclaimer of the subject matter recited therein. Applicants have amended claims 1, 25, 33, and 41 to recite that J and K may be taken together to form a 5 membered heterocyclic ring. Support for this amendment may found, for example, in the claims as originally filed and in the specification at Examples 1-24. In addition, claims 6, 28, 36, and 44 have been amended to depend from pending claims. No new matter has been added.

In the restriction requirement mailed March 21, 2003, the Examiner required restriction under 35 U.S.C. § 121 between the following allegedly patentably distinct groups of then-pending claims:

Group I: claims 1-16, drawn to a method of treating a neurological disorder in an animal comprising administering to said animal an effective amount of a compound of formula I;<sup>1</sup>

Group II: claims 1, 2, 11, and 17-24, drawn to a method for preventing neurodegeneration in an animal comprising administering to said animal an effective amount of a compound of formula I;

Group III: 1, 2, 11, and 25-32, drawn to a method for promoting neuronal regeneration and/or growth in an animal comprising administering to said damaged peripheral nerve [sic, animal] an effective amount of a compound of formula I;

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<sup>1</sup> Applicants note that although the Office Action refers to compounds of formula II, the pending claims are directed to methods of using compounds of formula I.

Group IV: claims 1, 2, 11, and 33-40, drawn to a method for stimulating the growth of at least one damaged peripheral nerve comprising administering to said nerve cell [sic, damaged peripheral nerve] an effective amount of a compound of formula I; and

Group V: claims 1, 2, 11, 41-48, drawn to a method for stimulating neurite outgrowth by a nerve cell in an animal comprising administering to said nerve cell an effective amount of a compound of formula I.

In response, Applicants elect to prosecute Group V, now comprising claims 1, 2, 11, and 41, 42, 44, and 45, with partial traverse with respect to the way the claims are grouped. In particular, Applicants believe that claim 2 should not be included in Group V. Claim 2 is limited to methods for stimulating the growth of damaged neurons, promoting neuronal regeneration, treating a neurological disorder, and preventing neurodegeneration. According to the Examiner, these methods are different from the claims of Group V, which recite methods for stimulating neurite outgrowth by a nerve cell. Because claim 2 does not recite a method for stimulating neurite outgrowth by a nerve cell, that claim is believed to be incorrectly included in Group V.

Additionally, Applicants wish to clarify that, with the exception of claims 1 and 11, none of the claims in Group V state that the neurite outgrowth by a nerve cell is *in an animal*.

Moreover, claim 1, which is a member of all five Groups identified by the Examiner, appears to be a linking claim as described in M.P.E.P. § 809.03. As such, the restriction requirement between the linked inventions should be **subject to the nonallowance of claim 1**. See M.P.E.P. § 809.03. Upon allowance of claim 1, the

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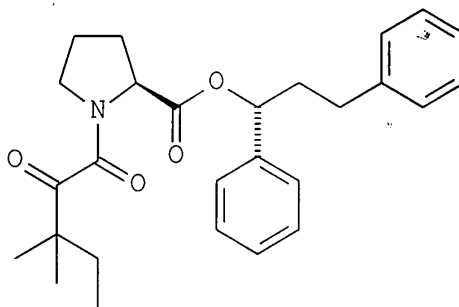
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requirement for restriction between Groups I-V should be withdrawn and all of the claims should then be examined. *See id.*

For the reasons above, Applicants respectfully request the reconsideration and correction of the restriction requirement.

The Examiner further required restriction within each Group between methods using formula I compounds having 5 membered and 6 membered heterocyclic rings. (Office Action, pages-3-4.) The amendments to claims 1, 25, 33, and 41 limit the pending claims to compounds in which J and K form a 5 membered heterocyclic ring. Applicants believe that this amendment is responsive to the Examiner's request and renders this aspect of the restriction requirement moot.

Finally, the Examiner directs Applicants to elect a single disclosed species within the claims of the elected group. (Office Action, page 5.) Applicants provisionally elect (1R)-1,3-Diphenyl-1-propyl (2S)-1-(3,3-dimethyl-1,2-dioxopentyl)-2-pyrrolidine-carboxylate (Example 11) with traverse:



All of the claims in Group V read on this species.

Applicants respectfully note that the Office has concluded several times that the immunophilin species encompassed by Formula I are not patentably distinct. For example, claims 1 and 4 of U.S. Patent No. 5,614,547 ("the '547 patent") to Hamilton et

al. encompass a genus of compounds that is virtually coextensive with the genus of Formula I. The instant application is a continuation-in-part of the '547 patent. Similarly, claims 2 and 6 of U.S. Patent No. 6,037,370 ("the '370 patent") to Armistead et al. encompasses a genus of compounds that is virtually coextensive with the genus of Formula II. Applicants noted this fact as required by 37 C.F.R. § 1.607 in the Transmittal Letter filed with the instant application.

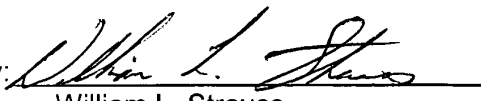
The M.P.E.P. is clear that an **"Election of species should not be required if the species claimed are considered clearly unpatentable (obvious) over each other."** M.P.E.P. § 808.01(a) (emphasis original). Here, having already issued at least two patents with claims encompassing the genus of Formula I, the Office cannot credibly assert that, if it were to find any species within Formula II unpatentable over the prior art, it would not insist that all species within Formula II were equally unpatentable. Under these circumstances, requiring Applicants to elect a single species for examination is inappropriate.

Applicants request the reconsideration and withdrawal of the species election requirement.

Please grant any extensions of time required to enter this response and charge any additional required fees to our deposit account 06-0916.

Respectfully submitted,

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